

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BAYER INTELLECTUAL PROPERTY )  
GMBH, ET AL., )  
 )  
Plaintiffs, )  
 )  
v. ) Civil Action No. 1:17-cv-00648-RGA  
 )  
SIGMAPHARM LABORATORIES, LLC, )  
 )  
Defendant. )  
 )

**DEFENDANT SIGMAPHARM LABORATORIES, LLC’S ANSWER,  
AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**

Defendant Sigmapharm Laboratories, LLC, by and through its undersigned counsel, and for its Answer responds to the separately-numbered paragraphs of Plaintiffs Bayer Intellectual Property GmbH, Bayer AG and Janssen Pharmaceuticals, Inc.’s Complaint, as follows:

1. Defendant admits that Plaintiffs’ Complaint purports to assert claims of infringement of U.S. Patent No. 9,539,218 (“the ’218 patent”) under the Patent Laws of the United States and, in particular, 35 U.S.C. § 271(e)(2); however, Defendant denies that there is any factual or legal basis for any of Plaintiffs’ claims against it in this action, and therefore, Defendant denies the allegations in this Paragraph.

2. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2 of Plaintiffs’ Complaint, and therefore, denies the same.

3. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3 of Plaintiffs’ Complaint, and therefore, denies the same.

4. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3 of Plaintiffs' Complaint, and therefore, denies the same.

5. Admitted.

6. Defendant admits that it is engaged in the development of unique generic and branded drug products and does so in compliance with the Federal Food, Drug, and Cosmetic Act. Except as so admitted, Defendant denies the allegations of Paragraph 6 of Plaintiffs' Complaint.

7. Admitted.

8. Defendant admits that it is engaged in the development of unique generic and branded drug products and does so in compliance with the Federal Food, Drug, and Cosmetic Act. Except as so admitted, Defendant denies the allegations of Paragraph 8 of Plaintiffs' Complaint.

9. Defendant admits that it is engaged in the development of unique generic and branded drug products and does so in compliance with the Federal Food, Drug, and Cosmetic Act. Except as so admitted, Defendant denies the allegations of Paragraph 9 of Plaintiffs' Complaint.

10. Defendant incorporates each of the preceding paragraphs in their entirety as if each is fully set forth herein.

11. Paragraph 11 of Plaintiffs' Complaint states legal conclusions to which no response is required. To the extent any response is required, Defendant admits that the Complaint purports to assert claims of patent infringement under the Patent Laws of the United

States, over which this Court has subject matter jurisdiction. Except as so admitted, Defendant denies the allegations of Paragraph 11 of Plaintiffs' Complaint.

12. Paragraph 12 of Plaintiffs' Complaint states legal conclusions to which no response is required. To the extent any response is required, Defendant admits that the Complaint purports to assert claims of patent infringement under the Patent Laws of the United States, over which this Court has subject matter jurisdiction. Except as so admitted, Defendant denies the allegations of Paragraph 12 of Plaintiffs' Complaint.

13. Defendant admits that it has consented to jurisdiction in this judicial district in Case No. 1:15-cv-00902-RGA; that the claims of patent infringement asserted in Case No. 1:15-cv-00902-RGA arise from the filing of ANDA No. 208546 and that Defendant asserted counterclaims in Case No. 1:15-cv-00902-RGA. Except as so admitted, Defendant denies the allegations of Paragraph 13 of Plaintiffs' Complaint.

14. Defendant admits that it consented venue in this District for the limited purpose of this Action. Except as so admitted, Defendant denies the allegations of Paragraph 14 of Plaintiffs' Complaint.

15. Defendant admits that the information set forth in Paragraph 15 appears in publicly available FDA documents. Except as so admitted, Defendant denies the allegations of Paragraph 15 of Plaintiffs' Complaint.

16. Defendant admits that the information set forth in Paragraph 16 appears in publicly available FDA documents. Except as so admitted, Defendant denies the allegations of Paragraph 16 of Plaintiffs' Complaint.

17. Defendant admits that, based on the face of Exhibit A of the Complaint, the '218 patent it issued on January 10, 2017 and is entitled "Prevention and Treatment of

Thromboembolic Disorders.” Except as so admitted, Defendant denies the allegations of Paragraph 17 of Plaintiffs’ Complaint.

18. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 18 of Plaintiffs’ Complaint, and therefore, denies the same.

19. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 19 of Plaintiffs’ Complaint, and therefore, denies the same.

20. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 20 of Plaintiffs’ Complaint, and therefore, denies the same.

21. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 21 of Plaintiffs’ Complaint, and therefore, denies the same.

22. Defendant admits that the ‘218 patent is listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (a/k/a the “Orange Book”) in connection with XARELTO. Except as so admitted, Defendant denies the allegations of Paragraph 22 of Plaintiffs’ Complaint.

23. Defendant admits that the it served a Notice Letter on April 12, 2017 in accordance with 21 U.S.C. § 355(j)(2)(B) and that said Notice Letter speaks for itself. Except as so admitted, Defendant denies the allegations of Paragraph 23 of Plaintiffs’ Complaint.

24. Defendant admits that the April 12, 2017 Notice Letter speaks for itself. Except as so admitted, Defendant denies the allegations of Paragraph 24 of Plaintiffs’ Complaint.

25. Defendant admits that the April 12, 2017 Notice Letter speaks for itself. Except as so admitted, Defendant denies the allegations of Paragraph 25 of Plaintiffs' Complaint.

26. Defendant admits that the content of ANDA No. 208546 speaks for itself. Except as so admitted, Defendant denies the allegations of Paragraph 26 of Plaintiffs' Complaint.

27. Denied.

28. Defendant admits that the April 12, 2017 Notice Letter speaks for itself. Except as so admitted, Defendant denies the allegations of Paragraph 28 of Plaintiffs' Complaint.

29. Defendant admits that the content of ANDA No. 208546 speaks for itself. Except as so admitted, Defendant denies the allegations of Paragraph 29 of Plaintiffs' Complaint.

30. Denied.

31. Defendant admits that it has knowledge of the claims of the '218 patent. Except as so admitted, Defendant denies the allegations of Paragraph 31 of Plaintiffs' Complaint.

32. Denied.

33. Denied.

34. Denied.

35. Paragraph 35 of Plaintiffs' Complaint states legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations in this Paragraph.

36. Admitted.

37. Defendant incorporates each of the preceding paragraphs in their entirety as if each is fully set forth herein.

38. Denied.

39. Denied.

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